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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,871	08/04/2003	Ronald F. Renzi	33413/US	5267

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Edward W. Bulchis
DORSEY & WHITNEY LLP
Suite 3400
1420 Fifth Avenue
Seattle, WA 98101

EXAMINER	
HYUN, PAUL SANG HWA	

ART UNIT	PAPER NUMBER
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,871	RENZI ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,9-21,57,58 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,9-21,57,58 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REMARKS

Claims 1-4, 7, 9-21, 57 and 58 were previously pending. In response to the Office action dated 11/17/06, Applicants added claims 61-63 and amended claim 11. In summary, claims 1-4, 7, 9-21, 57, 58 and 61-63 are currently pending.

The supplemental drawing sheet 13 submitted by Applicants has been acknowledged. Consequently, the objection to the drawings cited in the previous Office action has been withdrawn.

The amended Specification that reflects the submitted drawing sheet has been acknowledged.

The rejection of claim 11 under 35 U.S.C. section 112 cited in the previous Office action has been withdrawn in light of the amendment.

Despite Applicants' arguments, the art rejection of claims 1-4, 9, 10-21, 57 and 58 are maintained. The rejection of claim 7 has been withdrawn. However, upon further search and consideration, a new grounds of rejection has been made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **1-4, 7, 9-21, 57, 58 and 61-63** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 61 recite a seal that defines an area of fluidic communication between the inlet and the reservoir. The term "seal" suggests a barrier. Therefore, it is unclear how a "seal" can define an area of fluidic communication.

Claim **11** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "low dispersion" is indefinite because it is not clear what constitutes "low dispersion". The Specification does not provide a definition of "low dispersion" nor the range of values of dispersion-ability that constitutes "low dispersion". For examination purposes, any fluid channel will be deemed to be have "low dispersion properties".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **1-4, 9, 10-16, 18-21, 57, 58, 61 and 62** are rejected under 35 U.S.C. 103(a) as being unpatentable over Coville et al. (US 6,398,956 B1) in view of Coville et al. (US 4,695,430).

US 6,398,956 B1 ('965) discloses a microfiltration apparatus for processing biological fluids (see Fig. 3A). The apparatus comprises a base 14 comprising a needle 16 and a sealed reservoir 26 adapted to be pierced by the needle 16. The base 14 is sealed to a microfluidic chip 20 to define a separation channel 24. The microfluidic chip further comprises an inlet 11 in fluid communication with separation channel 24, a sample introduction port 15 in communication with inlet 11, and a filter 18.

The apparatus disclosed by '956 differs from the claimed invention in that the reference does not explicitly disclose 1) a detection module; 2) an interface; 3) a power module, or 4) an electrode. However, '956 does disclose that it is well known in the art to couple a microfiltration device to an automated apparatus to analyze the filtrate for various biological aspects, such as blood clotting time (see lines 18-23, col. 1).

US 4,695,430 ('430) discloses an apparatus for analyzing biological fluids contained in a single housing. The apparatus is adapted to be used with a microfiltration device (see line 61, col. 6). The apparatus comprises an optical detector for analyzing the filtered sample (see Abstract), an interface in the form of display 14 for displaying the results of the analysis, and a power source (see line 22, col. 19). '430 also discloses that it is well known to incorporate automated clotting time measurement means into such apparatuses. The clotting time measurement means comprises the use of a "fibrin switch" in which the physical formation of fibrin strands in a reaction mixture serves to

complete an electrical circuit between two electrodes, thus stopping a timer (see lines 50-63, col. 1).

In light of the disclosure of '430, it would have been obvious to one of ordinary skill in the art to couple the microfiltration apparatus disclosed by US '956 to an analyzer comprising an interface and a power module such as the one disclosed by US '430 so that the sample filtered by the microfiltration apparatus disclosed by '956 can be analyzed. It also would have been obvious to one of ordinary skill in the art to provide the reservoir of the modified apparatus with electrodes to enable the modified apparatus to measure clotting time of blood samples.

Although neither '956 nor US '430 disclose a plurality of reservoirs, microfluidic chips and detectors, it would have been obvious to one of ordinary skill in the art to provide a plurality of reservoirs and corresponding microfluidic chips and detectors to the modified apparatus to enable simultaneous sample processing. *See In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (holding that mere duplication of parts has no patentable significance unless a new and unexpected result is produced).

With regards to claims 13 and 14, the fact that a claimed device is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results. *See In re Lindberg*, 194 F.2d 732, 93 USPQ 23 (CCPA 1952).

Claim **7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Coville et al. in view of Coville et al. as applied to claims 1-4, 9, 10-16, 18-21, 57, 58, 61 and 62, and further in view of Sullivan (US 6,446,516 B1).

Neither Coville et al. references disclose a reservoir comprising multiple chambers.

Sullivan discloses an apparatus for conducting optical as well as electrochemical measurements of a fluid sample. The apparatus comprises a plurality of chambers, one chamber for conducting an optical analysis of the sample, and another chamber comprising electrodes for conducting electrochemical analysis of the sample (see lines 27-40, col. 4).

In light of the disclosure of Sullivan, it would have been obvious to one of ordinary skill in the art to partition the reservoir of the modified apparatus disclosed by '956 and '430 for conducting two different measurements of the sample. Naturally, it would have been obvious to provide electrodes in one chamber for conducting electrochemical measurements and fluidly connecting the other chamber to the separation channel so that it can be filtered prior to optical analysis.

Claim **17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Coville et al. in view of Coville et al. as applied to claims 1-4, 9, 10-16, 18-21, 57, 58, 61 and 62, and further in view of Strandberg, Jr. et al. (US 5,043,590).

Neither Coville et al. references disclose a laser diode. However, '430 does disclose that the optical detector can comprise an LED.

Strandberg, Jr. et al. disclose that a laser diode is superior to an LED because a laser diode has a lifetime of greater than 10 years and has the ability to focus beam to micro-size spots (see lines 55-65, col. 5).

In light of the disclosure of Strandberg, Jr. et al., it would have been obvious to one of ordinary skill in the art to use a laser diode as the optical means for analyzing the biological sample filtered by the modified apparatus disclosed by '956 and '430 because a laser diode has a lifetime of greater than 10 years and has the ability to focus beam to micro-size spots.

Claim **63** is rejected under 35 U.S.C. 103(a) as being unpatentable over Coville et al. in view of Coville et al. as applied to claims 1-4, 9, 10-16, 18-21, 57, 58, 61 and 62, and further in view of Chien et al. (US 2001/0052460 A1).

Neither Coville et al. references disclose a serpentine shaped channel.

Chien et al. disclose a microfluidic device comprising a microfluidic channel that is serpentine-shaped (see [0063]). The reference suggests that the shape enables the length of the channel to be increased without increasing the size of the device.

In light of the disclosure, it would have been obvious to one of ordinary skill in the art to shape the separation channel of the modified apparatus disclosed by '956 and '430 like a serpentine to optimize the length of the separation channel.

Response to Arguments

Applicants' argument with respect to claim 7 has been considered and it is persuasive. The rejection has been withdrawn, but upon further search and consideration, a new ground of rejection has been made.

Applicant's arguments with respect to the art rejections of claims 1-4, 9, 10-21, 57 and 58 have been fully considered but they are not persuasive.

Applicants argue that '956 fails to disclose a microfluidic chip comprising a plurality of inlets and a separation channel in fluid communication with the inlets. Applicants assert that the elements shown by '956 that correspond to the claimed "inlets" and "separation channel" are associated with the element corresponding to the claimed "fluid manifold", not the "microfluidic chip" as recited in the claims. This argument is not persuasive. As indicated in the rejection, the inlets and the separation channel disclosed by '956 are delimited by support/fluid manifold base 14. However, the inlets 11 and 27 are not part of the fluid support/manifold base 14. The support/fluid manifold base 14 disclosed by '956 merely comprises the tangible or solid material that makes up the support/fluid manifold base 14. The **holes** that define the inlets 11 and 27 are not part of the support/fluid manifold base 14. Likewise, the separation channel is defined by the grooves in the microfluidic chip 20. The inlets and the separation channel are bordered by the support/fluid manifold base 14, but they are not part of the support/fluid manifold base 14.

Applicants also argue that the piercing instrument 16 and reservoir 12 disclosed by '956 are part of the element that corresponds to the claimed "fluid manifold base",

not part of the "microfluidic chip" as recited in the claims. This argument is not persuasive because claim 3 explicitly recites that the reservoir and the needle are part of the fluid manifold base, not the microfluidic chip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
6/4/07

Jill Warden
Supervisory Patent Examiner
Technology Center 1700